

strategic partners or collaborators will not pursue alternative technologies or develop alternative products on their own or with others, including our competitors. We could have disputes with our existing or future strategic partners or collaborators. Any such disagreements could lead to delays in the research, development or commercialization of potential products or could result in time-consuming and expensive litigation or arbitration.

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<PAGE>

A SIGNIFICANT PORTION OF OUR REVENUES ARE GENERATED BY THE SALE OF PRODUCTS THAT ARE FORMULATED FROM ONE ACTIVE INGREDIENT.

Revenues from products whose active ingredient is omeprazole accounted for approximately 56% of our net sales in 2001. We currently purchase omeprazole from a single supplier. If we lose and cannot effectively replace this supplier or are otherwise unable to continue the sales of products that contain this active ingredient, our revenues would decline significantly.

IF OUR CLINICAL TRIALS FAIL, WE WILL BE UNABLE TO MARKET PRODUCTS.

Any human pharmaceutical product developed by us would require clearance by the U.S. Food and Drug Administration for sales in the United States, by Spain's Ministry of Health for sales in Spain and by comparable regulatory agencies for sales in other countries. The process of conducting clinical trials and obtaining FDA and other regulatory approvals is lengthy and expensive and we cannot assure you of success. In order to obtain FDA approval of any product candidates using our technologies, a New Drug Application must be submitted to the FDA demonstrating that the product candidate, based on preclinical research and animal studies as well as human clinical trials, is safe for humans and effective for its intended use. Positive results from preclinical studies and early clinical trials do not ensure positive results in more advanced clinical trials designed to permit application for regulatory approval. We may suffer significant setbacks in clinical trials, even in cases where earlier clinical trials show promising results. Any of our product candidates may produce undesirable side effects in humans that could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. We, the FDA or other regulatory authorities may suspend our clinical trials at any time if we or they believe the trial participants face unacceptable health risks or if they find deficiencies in any of our regulatory submissions. Other factors that can cause delay or terminate our clinical trials include:

- o slow or insufficient patient enrollment;
- o slow recruitment and completion of necessary institutional approvals at clinical sites;
- o longer treatment time required to demonstrate efficacy;
- o lack of sufficient supplies of the product candidate;
- o adverse medical reactions or side effects in treated patients;
- o lack of effectiveness of the product candidate being tested;
- o regulatory requests for additional clinical trials; and
- o instability of the pharmaceutical formulations.

OUR PATENT POSITIONS AND INTENDED PROPRIETARY OR SIMILAR PROTECTIONS ARE UNCERTAIN.

We have filed numerous patent applications and have been granted licenses to, or have acquired, a number of patents. We cannot assure you, however, that our pending applications will be issued as patents or that any of our issued or

determine the ultimate scope and validity of patents that are now owned by or may be granted to third parties, the extent to which we may wish or be required to acquire rights under such patents or the cost or availability of such rights.

Competitors may interfere with our patent process in a variety of ways. Competitors may claim that they invented the claimed invention prior to us. Competitors also may claim that we are infringing their patents, interfering with or preventing the use of our technologies. Competitors also may contest our patents by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our issued patents are not valid for a variety of other reasons as well. If a person claims we infringe their technology, we could face a number of consequences, including lawsuits, which take significant time and can be very expensive, payment of substantial damages for infringement, prohibition from selling or licensing the product unless the patent holder licenses the patent to us, or reformulation, if possible, of the product so it does not infringe, which could require substantial time and expense.

We also rely on trade secrets, unpatented proprietary technologies and continuing technological innovations in the development and commercialization of our products. We cannot assure you that others will not independently develop the same or similar technologies or obtain access to our proprietary technologies. It is unclear whether our trade secrets will be protected under law. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our information to competitors. Our employees and consultants with access to our proprietary information have entered into or are subject to confidentiality arrangements with us and have agreed to disclose and assign to us any ideas, developments, discoveries and inventions that arise from their activities for us. We cannot assure you, however, that others may not acquire or independently develop similar technologies or, if effective patents in applicable countries are not issued with respect to our products or technologies, that we will be able to maintain information pertinent to such research as proprietary technologies or trade secrets. Enforcing a claim that another person has illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

REGULATORY APPROVALS MUST BE OBTAINED AND MAINTAINED FOR PRODUCTS INCORPORATING OUR TECHNOLOGIES AND, IF APPROVALS ARE DELAYED OR WITHDRAWN, WE WILL BE UNABLE TO COMMERCIALIZE THESE PRODUCTS.

Government regulations in the United States, Spain and other countries have a significant impact on our business and affect the research and development, manufacture and marketing of products incorporating our technologies. In the United States, Spain and other countries, governmental agencies have the authority to regulate the distribution, manufacture and sale of drugs. Failure to comply with applicable regulatory approvals can, among other things, result in fines, suspension or withdrawal of regulatory approvals, product recalls, operating restrictions and criminal prosecution. In addition, governmental regulations may be established that could prevent, delay, modify or rescind regulatory approval of our products.

IF WE ARE UNABLE TO OBTAIN MARKETING APPROVALS TO SELL OUR PRODUCTS IN COUNTRIES OTHER THAN SPAIN, WE MAY NOT BE ABLE TO OBTAIN ADDITIONAL REVENUES FROM SALES IN THOSE COUNTRIES.

We cannot assure you that products that have obtained marketing approval in Spain will be approved for marketing elsewhere. If we are unable to obtain

Non-current assets:		
Fixed assets, net.....	5,595	4,139
Drug licenses and related costs, net.....	10,276	10,979
Other.....	409	655
	-----	-----
Total non-current assets.....	16,280	15,773
	-----	-----
	\$32,119	\$28,877
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable.....	\$ 4,820	\$ 2,645
Accrued expenses.....	2,490	968
Short-term borrowings.....	1,757	2,447
Current portion of long-term debt.....	--	738
Deferred income.....	496	2,564
	-----	-----
Total current liabilities.....	9,563	9,362
	-----	-----
Non-current liabilities:		
Foreign taxes payable.....	1,827	908
Long-term debt.....	142	623
Other.....	163	168
	-----	-----
Total non-current liabilities.....	2,132	1,699
	-----	-----
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$1.00 par value, authorized 2,000 shares, issued and outstanding, none.....	--	--
Common stock, \$.02 par value, authorized 35,000 shares, issued and outstanding, 14,585 and 13,914 shares.....	292	278
Stock purchase warrants (to purchase 3,424 and 4,038 shares of common stock).....	433	632
Additional paid-in capital.....	97,501	95,227
Accumulated deficit.....	(74,332)	(75,693)
Accumulated other comprehensive loss.....	(3,470)	(2,628)
	-----	-----
Total stockholders' equity.....	20,424	17,816
	-----	-----
	\$32,119	\$28,877
	=====	=====

</Table>

The accompanying Notes to Consolidated Financial Statements
are an integral part of these financial statements.

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<Page>

BENTLEY PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

AND OF COMPREHENSIVE INCOME (LOSS)

<Table>
<Caption>

	YEAR ENDED DECEMBER 31,		
	2001	2000	19
	-----	-----	-----
(IN THOUSANDS, EXCEPT PER SHARE DA			
<C>	<C>	<C>	<C>
Net sales.....	\$26,411	\$18,617	\$20,
Cost of sales.....	11,462	7,189	8,

MINUTES OF A MEETING OF THE BOARD OF DIRECTORS

Of

BENTLEY PHARMACEUTICALS, INC.

A meeting (the "Meeting") of the Board of Directors of Bentley Pharmaceuticals, Inc. (the "Company") was held at 9:00 a.m. Eastern time on January 28, 2001 at the Radisson Cable Beach Resort, Nassau, Bahamas. The following Board members were present:

James R. Murphy
Charles L. Bolling
Russell Cleveland
Miguel Fernandez
Robert J. Gyurik
Michael McGovern
William A. Packer
Michael D. Price
Robert M. Stote

being all of the members of the Board.

Also present at the Meeting, at the request of the Company, was Jordan Horvath, Vice President and General Counsel of the Company.

Mr. Murphy acted as Chairman of the Meeting and Mr. Price, at the request of the Chairman, acted as Secretary of the Meeting.

Mr. Murphy called the meeting to order and provided an update with respect to activities in Spain and the United States, including a discussion of new patents, product

B433

registrations, the sale of the rights to the product, Controlvas®, and licensing efforts. Discussion followed, including strategies to move the discussions underway to conclusion and definitive agreements.

Mr. Murphy followed this discussion with a presentation of expansion opportunities that included Teva, Bayvit, Gacell/Amerind and Grupo Industrial Farmex.

The Meeting was then recessed until 7:00 a.m. on January 29, 2001, at which time it reconvened.

Mr. Cleveland requested that he become a member of the Compensation Committee. After discussion, upon motion duly made, seconded and unanimously carried, it was

RESOLVED, that the Compensation Committee of the Board of Directors shall be comprised of Messrs. Bolling, Cleveland, Fernandez, McGovern and Packer.

Mr. Murphy indicated that the next item on the agenda was to approve the minutes of the Board of Directors meetings held on October 13, 2000 and December 22, 2000. After discussion, upon motion duly made, seconded and unanimously carried, it was

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RESOLVED, that the minutes of the Board of Directors meetings held on October 13, 2000 and December 22, 2000 are hereby approved.

Mr. Murphy suggested that the Company should consider retaining the services of an investment banker(s). Mr. Murphy presented information on Stonegate Securities, Inc. and their proposal to provide services to the Company. Questions and answers followed. Mr. Murphy then presented information with respect to other groups with whom he has held discussions, including Van Kasper, Sanders Morris Harris and Raymond James. After discussion, upon motion duly made, seconded and unanimously carried, it was

RESOLVED, that the engagement of Stonegate Securities, Inc. ("Stonegate") to perform certain investment banking services on behalf of the Company is hereby authorized and approved at a compensation rate not to exceed \$25,000 in cash and warrants to purchase up to 100,000 shares of the Company's common stock, the value of which warrants shall be offset against the fees payable to Stonegate in a private placement of securities in which Stonegate is the placement agent; and be it further

RESOLVED, that the officers of the Company are authorized to enter into an engagement letter or agreement with Stonegate which is no less favorable economically to the Company than is set forth above and with such other customary terms and conditions as are appropriate for agreements of this type.

Mr. Murphy then asked Mr. Price to present a financial report and Mr. Price did so, reviewing preliminary results for the year ended December 31, 2000 and the budget for the year ending December 31, 2001. Discussion followed with respect to budgeted

financial results, cash flows, and future expectations. In response to suggestions made, Mr. Price agreed to re-cast the 2001 budget, using an exchange rate of 185 pesetas per U.S. dollar, rather than 175 per dollar that was used in the budget presentation; to prepare and distribute annual comparisons of sales by product description; and to provide quarterly narrative financial reports in the future.

After discussion, it was preliminarily agreed that the next Board meeting would be held in North Hampton, NH on April 18-19, 2001 and that the following Board meeting would be held at the location of the Annual Shareholders' Meeting (to be determined) on June 14, 2001.

Mr. Price then provided a brief update of pending legal issues:

-Harshbarger

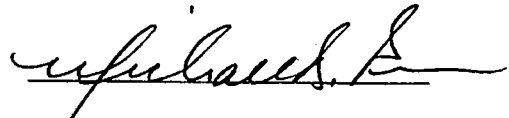
-Creative Technologies

Mr. Price informed the Board that the Company had reached a settlement of the Creative Technologies matter, by agreeing to pay to Creative \$140,000. After discussion, upon motion duly made, seconded and unanimously carried, it was

RESOLVED, that the agreement to settle the Creative Technologies legal matter by payment of \$140,000 is hereby ratified.

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There being no further business to come before the Meeting, upon motion duly made, seconded and unanimously carried, the Meeting was adjourned.

A handwritten signature in black ink, appearing to read "Michael D. Price", written over a horizontal line.

Michael D. Price, Secretary

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BENTLEY PHARMACEUTICALS, INC.

Agenda for Meeting of the Board of Directors

January 28-29, 2001

- I. Call to Order
- II. Approval of Minutes of Prior Board Meeting
- III. Report on Operations – Spain and US
- IV. Strategic Plan
- V. Acquisition Opportunity
- VI. Investment Banking
- VII. Projected Financial Results for 2000
- VIII. Budget for 2001
- IX. Schedule of upcoming Board meetings
- X. Review of Legal Issues
- XI. Other Business
- XII. Adjourn

B438

EXHIBIT

MURPHY

36

7/19/06

MB

ACTION ITEMS - For Friday 02-16-01

Comp Committee Rpt.

Mike	+	ATTACH sample of Bull
Bob	+	Comp. Cos.
? Jan 10% 2% increase	+	Amrix (Pfizer)
Tim	+	Amesin
Adolfo		

Follow-up - Plan response

Stonigall	King - Meeting	Adolfo - Call
	Rockett	Schiff
	Glaxo/SK	- Omeprazole
	Schiff Synthesis	Organic Patent
		- Sildenafil
		- P.R. Enalapril

? Patent - Synthesed opinion - PARACETOL
 * Testosterone Study

Aciclovir - Very Important (Sandoz-SKB/Glaxo)

? Franz Cell work vs. topical USA
 Hire formulation chemist - Sigma Help - Princeton

McNeil - New tablets PARACETAMOL - CALL
 - DATE FOR LAUNCH

Ethepharm - Meeting - severe flu
 ? Annoude omeprazole

Jim Gale - Analyst Rpt - Graytel, Prud Vector
 - GACel - when
 - Rpt of Meeting

Clinical - Acetaminophen

When - How much - Bob Stokes

Strategic Plan - CHRT, Gacel (Amesin)

* CALL Michael - scheduling

HIGHLY CONFIDENTIAL

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B439

02/16/01

Spain

ADOVED

20th Swiss Novartis

JUNE / July launch of 25 mg & 10 mg
Entacapril

28 + 56 per package

* Plantago Ovata

Launch 1st wk March

Patents Organic Omeprazole
Next FridayJan

Profit	Budget	Actual
Lab Belmont	40	60
Lab Denver	(3)	(2.5)

Controlvas 37 → 23 ml / month

US Dept Health + Human Services
Tom Thompson (New Head Man)

02-21-01 Knoll - Jordan Pollack
MAP Biotech - Rheumatoid Arthritis
* Pain Management - Emphasis
6 weeks -

Jenssen - Jeff Mathis
Left Message 609 730-2154

02-21-01 Adolfo

ZARAGOSA - Novartis visit
7-8 March to switch.
Ethypharm.

- Know now about Omeprazole
our own clients
- MOLT - Export by Lab Belmac
- Expect to transfer all but
organic formula

Redacted

Biorail Study
500 tablet dissolved
500 tablet SAH
1000 Sachet
500 Pennachol tubular

10 mil ptes.
Short time to
CMAX

B441

1. Maxigen - DNA gene modify potency
(MAXY) insulin modify possible
2. APPLIED molecular Evolution

Schering300k Shares w/in Group

✓ Earnings Profitable

✓ Patent acetaminol

(Estimate M

Tyneoul

Pannetol

New Pats

ADOLFO

Amox of Clavonic 2 Reg

1 Green ompregall

Ethylpharm - Marcit Phillip Boudal

Liquifa G.M (new)

Germany - omp.

Greece - omp.

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BENTL000104

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From: Paul Fitzgibbons**Sent:** Thu, 01 Mar 2001 20:22:32 GMT**To:** Jim Murphy; 'McGovern Mike (E-mail)'; 'Bolling Charles (Chick) (E-mail)'; 'Cleveland Russell (E-mail)'; 'Fernandez Miguel (E-mail)'; 'Packer William (E-mail)'; Bob Gyurik; 'Stote Bob (E-mail)'; Mike Price**CC:** Jordan Horvath**BCC:****Subject:** Operations Update - February 2001

Below is the Bentley Pharmaceuticals operational update which is periodically distributed to the Directors. The update highlights our activities as discussed at our operations/staff meetings. The update is organized into three areas: Spain Activities, Product Development, and Licensing Activities. Suggestions are welcome. Please contact Jim directly if you have questions related to any specific activity.

1. Spain Activities

- a. Sale of Controlvas (branded version of enalapril) to Shire - product sale completed November 21st with press release issued on November 28th. Final payment has been received.
- b. Filed new patent on paracetamol (acetaminophen). Processing worldwide patent filings through Ungria Associates.
- c. Received approval to market generic 2.5 mg and 10mg versions of enalapril in Spain where we will be first and only on the market. Scheduling March/April launch after receiving price allowance from Ministry of Health.
- d. Filed new patent for new galenic tablet formulation for omeprazole and other gastric sensitive drugs.
- e. Ethypharm - negotiations terminated due to lack of full commitment from Ethypharm.
- f. Teva - reviewing Omeprazole for other European markets. Teva has also expressed interest in our nail lacquer. We are attempting to present our technology to the Philadelphia group at the suggestion of corporate executives from Israel, and we are also planning a second presentation for Europe in March.
- g. A new patent is being prepared for our organic formulation process for omeprazole and should be finished on March 9th.
- h. Novartis has performed due diligence on our manufacturing site. We will be awarded a contract for manufacturing from them. They commented that our site is of higher quality than their own in Switzerland.
- i. Lab. Belmac and Lab. Davur will soon receive generic registrations of Augmentin® in return for a copy of our generic dossier for omeprazole.
- j. Lab. Davur was granted Ministry of Health approval to market a new presentation (250ml) of Codeisan®.
- k. Our omeprazole has been approved for export to Greece and Lebanon.

2. Product Development

- a. Onychomycosis (Nail Lacquer) - The University of Alabama Birmingham IRB approved additional toenail study and extension of fingernail trials. Fingernail: 19 patients enrolled. Toenail: 20 subjects cultured for screening. Expect 25 total to participate. As a follow-on to last year's provisional patent filing, we filed a non-provisional (final) patent for our nail lacquer worldwide on February 16th.

BENTL024104
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b. Intranasal Insulin - Located potential source of supply in Brazil and obtained sample supply of human insulin. Planning to conduct initial formulation development with UNH. Other sources of insulin supply in China are also being looked at. Also, will be filing provisional patent for intranasal delivery soon.

c. Auxilium A2: Testosterone for men - Initial results of Auxilium's NDA clinical trials (Bentley t-gel with CPE 215 vs. Unimed's Androgel) show only modest advantage for Bentley t-gel. We may be able to compare a lower dose of our gel vs. the higher dose of Androgel.

d. Dartmouth - Furthering use of our exclusive patent license from Dartmouth for treatment of Fibromyalgia and Chronic Fatigue Syndrome (FMS/CFS), we have obtained approval for a new grant from the New Hampshire Industrial Research Center (NHIRC). The grant involves treatment of women having FMS/CFS with testosterone and other androgens. We plan to start this study in humans in early May at the Dartmouth-Hitchcock Medical Center. We are currently preparing protocols.

e. University of New Hampshire Studies - Two studies (grants from the NHIRC) are continuing: 1) formulation studies for nail lacquer, intranasal spray; and 2) hormone gels and intranasal spray testing in animals. A third grant application for a study of the growth hormone (GnRH) for fertility studies is planned for submission in early March.

f. Clinical study of paracetamol is scheduled for April in Ireland. Our 1 gm sachet and 500 mg tablet swallowed and 500 mg tablet dissolved will be compared to a reference drug Panadol® and/or Tylenol®.

3. Licensing Activities

a. GlaxoSmithKline - visited week of February 12th. They continue to have strong interest. Their interest is in several areas: worldwide use of our paracetamol patent, omeprazole tablet, nail lacquer, acyclovir, and topical diclofenac. Updated product profiles sent to them. They want to see results of bioavailability testing of paracetamol (April in Ireland). Also regarding this, they have questions about dissolution, speed of onset, and taste.

b. Sanofi Synthelabo - visited week of February 12th. They are Interested in our paracetamol and lacquer, and a newly prepared cream formulation of acyclovir. Their Technical Review committee and Marketing committee have given the go ahead for acyclovir and asked for a supply quote for 500,000 units/year of paracetamol. They are requesting a term sheet for the territory of France.

c. Reckitt-Benckiser - visited week of February 12th. They are interested in paracetamol sachet and lacquer. A confidentiality agreement has been signed and they requested ½ kilo of paracetamol for formulation purposes.

d. Schering-Plough - has our nail lacquer under committee review, however, they are proceeding very slowly. We have been working alternative contacts that may assist in speeding up committee action. At this point we anticipate a Schering-Plough decision in early-mid March.

e. McNeil - expressed interest in nail lacquer and also paracetamol. Samples and copy of patent provided to them. Visit planned for March 12th to present the lacquer to the Medical review committee.

f. Shire USA - Oral drug development collaboration. Provisional patent to be completed in March. Collaboration action intentionally postponed pending resolution of potential conflict of interest (Amarin drug delivery division in Europe).

g. Pfizer - four studies in process: 1) veterinary in U.K.; 2) solubility studies in animals at Groton, CT; 3) animal studies (pigs) at Warner-Lambert site in Ann Arbor, MI.; and 4) potential use of compounds for topicals (acne). Pfizer reported formulation success with the initial evaluation in the UK. We provided information on

B444

the patents, cost, manufacturing, and DMF. The initial studies in Ann Arbor, MI apparently showed some success, warranting further study with an additional 6-9 formulations. Pfizer interest remains high.

h. Lohmann - interest in developing a testosterone patch for treatment of Fibromyalgia. Their proposal is under review. We would prefer development of other existing gels for those indications where CPE-215 would be a value-add.

Paul Fitzgibbons
Director of Special Projects
Bentley Pharmaceuticals, Inc.
603-964-8006 (office) 603-964-6889 (fax)
pfitzgibbons@bentleypharm.com

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3/14/01

TELEPHONIC BOD MEETING

Nomination:

Approval New stk option

Annual mte.

D&T for next yr.

MOVE IRM in New class

3-14-01

AMARIN - Jim Galt

Development contracts

5 mil Royalty Stream in 2003

Break even

3-14-01

ADOLFO

Monthly Sales JAN - FEB - YTD MAR.

Announcements - Omeprazole (3 Months)

Price issue - 2.5 + 10mg. Enalapril

18.4 million sales 2000

PHARMINDUSTRY TAX - report

For 30K million pesos
Now 5000 - R+D

2001 - Renewal

Ethypharm - Pierre Gaudin Fired

last

1998 39
1999 262001 - New Agreement
Signed Yesterday

3-22-01 Spain

Announcement May

Novartis contracts

- ① 5 to 10 years w/ min/yr.
 machinery zoom psts - Free
 Fluid Bed Extrusion
 Next month April

- ② More products in future
 Tablets etc.

280 mil tablets

Value Est. 55 mil. psts

But 70 mil psts

Investment

- ③ Ethypharm France 60% to
 US NICARDIENE

Portugal Helm

LAVISSAL - orderApril
 Announc.

✓	Doctors Trimet.	40K Euros
✓	Simvats.	55K "

5 yr. Supply

Reckitt

100Kg from Italy 6 April

Ethypharm - Adolfo Basilio

Diltizen purchase 4 mil. psts

Enalapril 2.5 & 10mg. was 38% of 8M \$

MOH - will increase

SGC - decrease

WAGEN - Next 27M

Launched June

> 75% 6M

3/27/01 Adolfo mtg.

B447

Novartis

Fenistil pellet.

Equipment - > 1 mil USD

2 * Enalapril 2.5mg, 10mg

May 15th - June 1 Announce

3 ~~Paracetamol~~ Bio-study COST \$100,000

Manufact. 4 April

Analy. 10 "

10 May start study

NGG
NGG

✓ Tylenol - 500mg all same lot (200)

✓ Paracetol - " (200)

4 * Omeprazole - Dr. Reddy Source of Active
From FDA cert. India
Saves ~ \$1 mil / year

Redacted

ADOLFO ?

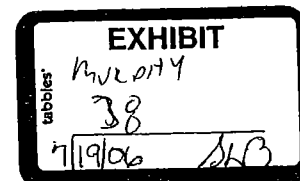
Simvastatine

Protocol - Ireland

Portugal

Portugal

Paracetamol - Sanofi



B448

Paracetamol

Benelux, Hungary, Germany
80 mil tablets 500mg.

Patents Omeprazole

Submitted 1. Microtablet Omeprazole
or res. tabletSubmitted 2. Micropellets new Improved process
for granulationsame Patent { Cooper. 3. Omeprazole - under vacuum
eliminating step
Patent Lansiprazole

1. Process Patent

NEED API Source

NEED DMF

Patent Paracetamol - Filed Nov 2000

Ungaris will File by Nov 2001
in other Countries

KVA Quote Paracetamol

0.70 Eurocents For Finished 20#
For Packaging Alum/Alum
in 1300

\$2.5 mil sales @ 50% GM

\$		→	Euro	/	.95	.90
100,000						
50,000			.95			
200,000			.90			
250,000			.85			
300,000			.80			

B449

3 April 01 SPAIN

Belmar

Spec. 235 436

manf. 41 172

276,608

19333.33

Dayun

81,058

August Installation Machinery - Omeprazole

600 Kg capacity

300 Kg "

Paracetamol - Italy 100 Kg

Tablets -

Uquifa - Greece Omeprazole

3 shifts 7 days / week - Omeprazole

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BENTL001158

B450

Adolfo

Ignacio (Ethypharm) Alvarez

15 Dec. Proposal

Contract 5% royalties ^{Belmar 201} other customers
 Supply Agent - Organic
 then Aqueous formulation

20 Mar. 2000 contract (exp. Mar. 2002)
 ↳ will not limit

Addendum - 20 mg., Patent of Ethypharm

→ Patent file 6 Apr. 2001

Paracetamol

Solubilization 99% after

200 mg 500 Panadol

Helm - Omeprazole

License 30% royalty

5% to Helm AG

Order Dom Rep. \$30K order

Omepr

Loper

Controlvas (bulk for packaged)

Antibiotics

Cantabrin - Paid 2nd 10 million pesos

2001

1. L Bel LAB DAVR Rinafara

2. Manufacture

3. OPL Development

simvastatin, Trimethoprim
 Lanthopranolol, Pentoxifylline,

5-22-01

B451

SEHERING - Nancy Rich

MEETING

Lamisil

Sporonox

- Diff. to switch to OTC
Problem

- Passing - on DEAL for Lacquer

Craig Benson
PAUL

corporate

5-23-01

Spain / mille Pucci

1. LOREISSAL AGENTS (Signed)

5 Yr. Supply Agmt.

2. Amrentedene By August

11 Mil

11 Mil

8

3. 15% reduction Prices

Attorneys Say Fight

4. Ethypharm - EXPIRE MAR. 2002

- 6 month notice required Sept

5. Norartis -

Ethypharm 11 K / Kg

our price 21.6 K / Kg

By August if any

6. 300 Kg March July

600 Kg March Sept

On sample

EXHIBIT

N/6/04

39

7/19/06

SBC

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BENTL001198

B452

Atrix Program Structure

SAFETY

SPAIN

15 JUNE Launch Enalapril new doses

Ethypharm

- CONTRACT - Atty. want - Now
- SEND TO J Murphy
- CONTRACT - Organic formulation
10 yrs H₂O
Manuf.
Nothing of Aquas Formulation
LeDuc - ASKED to CANCEL meeting

2 MACHINES. ORSAS

300 kg
600 kg

- Announce New patent - After Mtg next wk
- 350 mill profit
E-mail BL

NOVARTIS - GM SPAIN

Ethypharm 12K/kg Quoted

Lab Belmac 21K/kg Quoted

.9 parts / capsule
Filling

SALGS - Over Budget BELMAC + DAVAR

Enal.

Pantoyphillia - Aug. in supply

Adolfo

B453

1. Insurance Coverage
2. Antigien
3. TEVA
4. SHK OPTIONS

Spain: Private Placement then IPO

5. Rx Dan, Josh

Ethepharm - Mtg. Phillippe Boudal

Contract send to J. Murphy

3rd Machine - requested - no Answer
Aq. Formulation

Future Relationship?
Diltiazem - dead

TEVA

Dossiers have 3 Need additional Info
Ltrs needed

Bristol

Arizamol - want to cancel

LB was Now
64 → 140 ml

BMS was
360 296

• No Golf Course

5-22-01

B454

SEHERING - Nancy Rich

Meeting

Lamisil

Sporonox

- Diff. to switch to OTC
Problem

- Passing - on Deal for Lacquer

Craig Benson
PAUL

corporate

5-23-01

Spain / mille Price

1. Larissal Agmts (Signed)

5 Yr. Supply Agmt.

2. Amantadene By August

11 Mil

11 Mil

8

3. 15% reduction Prices

Attorneys Say Fight

4. Ethypharm - Expire Mar. 2002

- 6 month notice required Sept

5. Norartis -

Ethypharm 11 K / Kg

our price 21.6 K / Kg

By August if any

6. 300 Kg mach. July

400 Kg mach. Sept

On request

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<http://www.ethypharm.com>

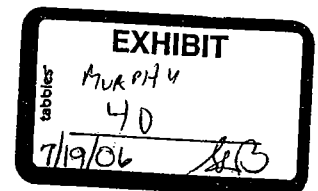
• Tel	+33 1 4112 1720
• Fax	+33 1 4112 1730
• E Mail	contact@ethypharm.com
• Visioconf	+33 1 4112 0075

194, Bureaux de la Colline - 92213 SAINT CLOUD CEDEX- FRANCE

To	Mr James MURPHY	From	Mr Gérard LEDUC
Cie	BENTLEY	Cc	Roseline JOANNESSE
Cc		Fax	+33 1 4112 1745
Fax	00 1 603 964 6889	Tel	+33 1 4112 1720
Tel	00 1 603 964 8006	e-Mail	Leduc.gérard@ethypharm.com
	32 (cover page included)		June 8, 2001
Page(s)		Date	

Attached :

- * Letter from Gérard LEDUC
- * Draft of Agreement - Belmac



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EP 002009

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Attached :

- * Letter from Gérard LEDUC
- * Draft of Agreement - Belmac

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5) Pas de réponse

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T T I ETHYPRARM ST CLOUD 33 1 41121718

*** Rapport de TRANSMISSION (8. Jun. 2001 15:45) ***

P. 1

EP 002010

B457



BENTLEY Pharmaceuticals Inc.
65 Lafayette Road, 3rd Floor
North Hampton,
NH 03862-2403
USA

Saint Cloud, June 8th, 2001

For the attention of Mr James R. MURPHY

Dear Sir,

Further to our discussion of the beginning of year 2001, please find attached a draft of agreement aiming at regularizing the relationship between Ethypharm and Belmac.

In the course of the past weeks, it seemed that the relations between heads of our companies (industrial, legal etc..) became strained. We deeply regret this situation and hope that everyone will understand that we wish to maintain long term and good relationship with your group and that we do not intend to reach a situation of conflict which, in our opinion, would damage both companies and which, in any case, is not appropriate.

This is the reason why I propose that you and me alone, or if necessary, assisted by one of our lawyers, discuss this draft of agreement.

If you agree, we could meet, preferably in Paris, between the 3rd and the 6th of July 2001.

I look forward to hearing from you on this subject,

Yours Sincerely,

Gérard LEDUC
General Manager

Siège Social 21, rue Saint Matthieu F-78550 Houdan Tél : + 33 - 1 30 88 17 20 Fax : + 33 - 1 30 88 17 30	Head Office 194, Bureaux de la Colline - Bât. D F-92213 Saint-Cloud Cedex Tél : + 33 - 1 41 12 17 20 Fax : + 33 - 1 41 12 17 30	Site R & D - Z.I. de Saint Arnoult F-28170 Châteauneuf-en-Thymerais Tél : + 33 - 2 37 65 88 00 Fax : + 33 - 2 37 51 02 88	Site R & D - 1900, Route des Grèves Les Collines de Sophia F-06560 Valbonne Tél : + 33 - 4 92 96 09 59 Fax : + 33 - 4 92 96 09 60	Site R & D - Château Bersol 218-228, Av. du Haut-Lévêque F-33600 Pessac Tél : + 33 - 5 57 26 56 76 Fax : + 33 - 5 57 26 56 77
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S.A. au capital de 6 000 000 F - RCS Versailles - Siret 311 999 833 00032 - APE 244 C
Web : <http://www.ethypharm.com> - E-mail : contact@ethypharm.com - Vidéoconférence : + 33 - 1 43 17 00 75

EP 002011

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TECHNOLOGY LICENCE
AND
MANUFACTURING AGREEMENT

BETWEEN THE UNDERSIGNED :

ETHYPHARM SA - with corporate domicile at Marques de la Ensenada, 16 28004
MADRID – SPAIN

A company belonging to **ETHYPHARM S.A.** 21 rue Saint Matthieu 78550
HOUDAN – France

Hereinafter called **ETHYPHARM**

Represented by its President : Mr Patrice DEBREGES

OF THE ONE PART,

AND :

LABORATORIOS BELMAC S.A. with corporate domicile at C/ Montearagon 9, -
28033 MADRID - SPAIN

A company belonging to **BENTLEY Pharmaceuticals Inc.** – 65 Lafayette Road, 3rd
Floor, North Hampton, NH 03862-2403 – USA

Hereinafter called **BELMAC**

Represented by its Executive Director : Mr James R. MURPHY

OF THE OTHER PART

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WHEREAS :

- 1) **ETHYPHARM** is a pharmaceutical company specialized in the development, registration, manufacturing and licensing of pharmaceutical specialities and owns any and all relevant equipment, technology, know how and patents
- 2) **BELMAC** is a pharmaceutical company specialized in the development, registration, manufacturing, licensing and marketing of pharmaceutical specialities and owns any and all relevant equipment, technology, know how and patents.
- 3) **ETHYPHARM** and **BELMAC** have been cooperating since 1990 for the manufacture, control, and/or encapsulation and/or conditioning in **BELMAC's** Premises (as defined below) of some of **ETHYPHARM's** products, listed in the attached Annex A ("the Products" as defined below) licensed and sold by **ETHYPHARM** to **BELMAC** and **BELMAC's** Licensees (as defined below) in Spain and to other customers of **ETHYPHARM** in Spain and outside Spain.
- 4) This cooperation, has proceeded by agreement but has never been fully confirmed through a formal Agreement signed by both parties. Nevertheless, various documents, listed in the attached Annex B, have been signed, in the past, by the Parties in order to comply with administrative requirements or to specify particular obligations of the Parties concerning this cooperation.
- 5) Throughout the term of the cooperation mentioned in point 3) herein above, **ETHYPHARM** has subcontracted the manufacturing and control of the Products to **BELMAC** for manufacture and control in the Premises. Said Premises have been initially equipped, at **ETHYPHARM's** expenses and on the basis of Quality Assurance procedures and instructions transmitted by **ETHYPHARM** to **BELMAC**, in order to enable **BELMAC** to carry out the manufacture of **ETHYPHARM's** products in full compliance with GMP regulations in force in Spain. As a consequence of the work performed by the Quality Assurance Department of **ETHYPHARM** in collaboration with **BELMAC** and on the basis of the relevant

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documentation established and provided by **ETHYPHARM**, the Premises have been GMP approved by the Spanish Health Authorities in September 1992. Since 1998, the Quality Assurance Department of **BELMAC** has been responsible for the good compliance of the Premises with GMP's in force in Spain and for audits performed by the Spanish Ministry of Health and Customers and Licensees in this respect.

- 6) All of the machinery and equipments set in the Premises used to manufacture and control **ETHYPHARM**'s products, except for specific equipment used in the control of the Products, have been purchased by **ETHYPHARM**.
- 7) **ETHYPHARM** has insisted that **BELMAC**'s technicians dedicated to its Products be trained locally by **ETHYPHARM** to manufacture and control of the Products at the Premises in accordance with GMP practices.
- 8) Within the framework of this continuing agreement and cooperation, **ETHYPHARM** has communicated to **BELMAC** confidential information which includes, but is not limited to, documentation relative to manufacturing processes and formulae, manufacturing and control know how, patents, quality and analytical procedures as well as other information included in the Registration Files of the Products needed by **BELMAC** to perform its manufacturing and control obligations.
- 9) **ETHYPHARM** worldwide pharmaceutical operations now require it to manufacture at its own production sites in France part of its production of Products, previously entrusted over the past years to **BELMAC**.
- 10) As a consequence and to clarify the understanding between the two companies, **ETHYPHARM** and **BELMAC** have agreed to redefine the framework of their cooperation, and the conditions of use by **BELMAC** of the Technology licensed by **ETHYPHARM** to manufacture and control the Products both for **ETHYPHARM** and its Customers and for **BELMAC**'s and its Licensees.

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The parties, having regard for that stated above, with the express intention of reflecting their respective obligations in a written and binding agreement, and mutually acknowledging each party's capacity thereon, have decided to subscribe the present agreement (hereinafter, « the Agreement ») in accordance with the following clauses.

CLAUSE 1 — DEFINITIONS

- 1.1. **Affiliate** shall mean any entity which controls, is controlled by or is under common control with either BELMAC or ETHYPHARM for so long as such control exists. An entity shall be regarded as in control of another entity for purposes of this definition if it owns or controls, directly or indirectly, more than fifty per cent (50%) (or with respect to an entity formed under the laws of another jurisdiction, such lesser percentage that is the maximum allowed to be owned by a foreign corporation in such jurisdiction) of the equity of the subject entity having the power to vote on or direct the officers of the entity ; except to the extent such entity is precluded by contract from exercising such control.
- 1.2. **Customers** shall mean a non-Affiliate third party whom promotion, distribution and marketing rights on the Products have been granted by ETHYPHARM in and outside the Territory
- 1.3. **“ETHYPHARM”** shall include any Affiliates involved in the activities envisaged in this Agreement.
- 1.4. **“ETHYPHARM Know How”** shall mean any proprietary information owned by ETHYPHARM or its Affiliates in relation with the Technology and the Products

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1.5. "ETHYPHARM Patent rights" shall mean all ETHYPHARM rights in and to :

- 1.5.1. Those certain patent granted and patent applications listed in Annex A hereto (ETHYPHARM Existing Applications), and,
- 1.5.2. any foreign counterparts of the Existing Applications, and all divisions, continuations, continuations-in-part, patents of additions, and substitutions of and all patents issuing on, any of the foregoing, together with all registrations, reissues, reexaminations or extensions of any kind with respect to any of such patents, in each case to the extent the same claim and disclose subject matter disclosed in the Existing Applications.

1.6. "Licensees" shall mean a non-Affiliate third party whom promotion, distribution and marketing rights on the Omeprazol Product have been granted by BELMAC in the Territory

1.7. "Party" or "Parties" shall refer individually or collectively to BELMAC and/or ETHYPHARM

1.8. "Premises" shall mean BELMAC's factory located at Zaragoza, Poligono Malpica Calle C 4 (Spain).

1.9. "Product" or "Products" shall mean the pharmaceutical products listed in Annex A to this Agreement, including Omeprazol Product as defined below, and for which ETHYPHARM has entrusted the manufacture to BELMAC.

1.10. "Omeprazol Product" shall mean the pharmaceutical product listed in Annex A and containing Omeprazol as sole active ingredient.

1.11. BELMAC" shall include any Affiliates involved in the activities envisaged in this Agreement.

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- 1.12. "Registration File" shall mean the dossier submitted to the competent authorities in order to obtain the authorization to market the Product in or outside the Territory.
- 1.13. "Technology " or "Technologies" shall mean any proprietary information owned by ETHYPHARM and its Affiliates consisting of know-how (including but not limited to secrets, patents both pending and granted), methods, processes, formulae, techniques or data necessary for the manufacture, control, sale, import or use of Products as well as any improvements made on, but not limited to, formulae and manufacturing process of the Products during the past collaboration between the Parties.
- 1.14. "Territory" shall mean Spain.

CLAUSE 2 - SUBJECT

The subject of this Agreement is to confirm the terms and conditions which will be applied, from date of signature of the present Agreement, to the business relationship under which BELMAC will be granted a licence to use the Technology, ETHYPHARM's Know How, ETHYPHARM's patent rights and equipment to manufacture and control of the Products both :

- for the sale of the Omeprazol Product, purchased exclusively from ETHYPHARM, by BELMAC and its Licensees in the Territory and,
- for the sale of the Products to ETHYPHARM's Customers in and outside the Territory.

In the event, BELMAC or its Licensees wish to export the Omeprazol Product to countries outside the Territory, BELMAC agrees to request for itself and its Licensees, on a case by case basis, prior written approval from ETHYPHARM. Such approval may be refused by ETHYPHARM, whatever the reason, including, if ETHYPHARM estimates that such extension of the Territory may alter its relationship with third parties or jeopardize or create interference with

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ETHYPHARM's intellectual property rights or for any other legal or contractual reason.

- 11) For the sake of good understanding it is hereby specified that **BELMAC** has been granted marketing authorizations on Omeprazol Product (as defined below) in Spain which are used directly by **BELMAC** and by its Licensees to market the Omeprazol Product in the Territory. Said marketing authorizations have been obtained on the basis of technical documentation originating from **ETHYPHARM** and subject to the present Agreement and additional work (such as stability, bioequivalence, validation) performed directly by **BELMAC**.

CLAUSE 3 – RIGHTS

BELMAC acknowledges that the rights granted by **ETHYPHARM** in the present Agreement on, but not limited to, the Technology, **ETHYPHARM's** Know How and **ETHYPHARM's** patents and equipment and their use by **BELMAC** are strictly limited to the cooperation, as organized in the present Agreement, between **ETHYPHARM** and **BELMAC** and **BELMAC** recognizes that this does not constitute a transfer of Technology and does not grant **BELMAC** rights to use the above mentioned elements to manufacture and to sell the Products otherwise than as specified in the present Agreement.

CLAUSE 4 - RESOURCES

4.1. Location and Premises

The manufacture and control of the Products shall take place at the Premises located at Poligono Malpica Calle C 4., in Zaragoza (Spain) which have been GMP approved in September 1992 as mentioned hereinabove. **BELMAC** may not change location of the Premises without prior approval of **ETHYPHARM**.

BELMAC shall be responsible for keeping said premises in a good sanitary, safe and steadily workable conditions during the term of this Agreement and the Quality Assurance Department of **BELMAC** shall continue, as organized since 1998, to achieve all modifications in the Premises in order to maintain cGMP conditions and

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minimum requirements from ETHYPHARM in terms of Quality Assurance procedures.

BELMAC will allow, at any time in case of specific concern in the manufacturing and control of the Product or after prior notification of two weeks in the event of regular audit, ETHYPHARM, its employees, representatives and Customers to have convenient and continuous access to the Premises in order to audit the conditions of manufacturing and control of the Products.

BELMAC, when audited by its Licensees, will indicate to said Licensees that the Omeprazol Product is manufactured with machinery, equipment, Technology and Know How pertaining or under licence from ETHYPHARM

4.2. Machinery and Equipment

It is hereby recalled, that the machinery and equipment used to manufacture the Products will remain the exclusive property of ETHYPHARM and may not be used by BELMAC otherwise than for the purpose of manufacturing and controlling the Products as provided for in this Agreement. Details relative to the investment made by ETHYPHARM at BELMAC's Premises and the updated list of the machinery and equipments belonging to ETHYPHARM are indicated in Annex C to this Agreement. The Parties estimate that the present equipment and machinery shall offer sufficient capacity to enable BELMAC to manufacture both for ETHYPHARM's customers, BELMAC and BELMAC's licensees needs.

The present capacity of the equipment dedicated to the manufacturing of the Products is estimated at :

- 110 millions doses of Omeprazol Product per annum corresponding to eight batches of Omeprazol Product containing 1 250 000 doses each per month , (one dose being the content of one capsule manufactured in GS pans.
- 130 millions doses of Products per annum, except for Omeprazol Product, manufactured in classical pans.

The production schedule and the splitting of the above mentioned capacity between the Products ordered shall be subject to regular agreement between the production managers of each of the Parties.

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BELMAC shall be responsible for maintaining any and all machinery and equipment entrusted by ETHYPHARM in perfect working conditions for the production of the Products and shall be responsible at its own cost for daily maintenance, the compliance of regular maintenance as planned by ETHYPHARM as well as any repair of damages.. Payment of any spare parts, validation and testing of the equipment shall remain to the charge of ETHYPHARM. Moreover, BELMAC shall keep ETHYPHARM, regularly and with sufficient anticipation, informed of specific maintenance and repairs to be performed on the machinery and equipment in order not to delay production of the Products.

4.3. Documentation

All and any documentation, procedures or other information on ETHYPHARM's Know How and ETHYPHARM's Patent rights communicated or transmitted by ETHYPHARM to BELMAC or its personnel, within the framework of the cooperation described in this Agreement and needed to manufacture and control the Products, are considered as ETHYPHARM's sole property, which is acknowledged by BELMAC and is subject to confidentiality. ETHYPHARM must approve of BELMAC's use of said documentation, procedures and information may not be used by BELMAC, or its personnel for any other purpose than that described in the present Agreement.

4.4. Personnel

Personnel involved in the manufacturing and controlling of the Products shall remain employees of BELMAC. In order to check the qualification of said Personnel for the purpose of this Agreement, ETHYPHARM will have the possibility to test BELMAC's personnel enrolled to manufacture the Products and only those duly accepted by ETHYPHARM shall be considered as part of the personnel authorized to manufacture the Products.

Members of BELMAC's personnel involved in the production of the Products will be clearly identified in a separate document annexed to this Agreement and which may be modified only by written agreement between the parties. The parties agree to designate and train to the manufacture and control of the Products more technicians than actually needed in order to avoid shortage of qualified and accepted personnel.

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Moreover said members will be bound by the Confidentiality Clause subscribed by BELMAC as provided in Clause 11 hereunder and BELMAC shall be fully responsible for the compliance of the members of its personnel with said clause.

CLAUSE 5 - TERM, TERMINATION AND CONSEQUENCE OF TERMINATION.

5.1. Term

The effectiveness of this Agreement will apply as from January 1st, 2001 and shall remain in force for an initial period of three (3) years.

Six months prior to the end of the initial period of three (3) years, the parties agree to meet in order to discuss the renewal of this Agreement.

In the event, the parties do not confirm in writing the renewal of this Agreement, this Agreement will be considered as automatically terminated.

5.2. Termination

Each party reserves the right to cancel this Agreement if the other party commits a material breach of its obligations and fails to remedy this breach within ninety (90) days of the notification of said breach by registered letter, without prejudice to any other actions that the non-defaulting party may exercise and particularly to a claim for damages.

This Agreement will be automatically terminated at the date a specified event occurs and without prejudice to the dispositions of the applicable law, namely if one of the Party is dissolved or liquidated, files or has filed against it a petition under any applicable bankruptcy or insolvency law, or makes a general assignment for the benefit of its creditors.

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5.3. Consequence of Termination

Upon termination of this Agreement, ETHYPHARM is entitled to move out, at ETHYPHARM's costs (except if termination is due to a breach of its obligation by BELMAC in which case removal will be at BELMAC's costs) any furniture, equipment, apparatus, machinery identified as belonging to ETHYPHARM, mentioned in Annex D to this Agreement.

Upon termination of this agreement for any reason, BELMAC shall cease the manufacturing of the Products and will return promptly to ETHYPHARM any and all information and data received from ETHYPHARM herein, without retaining any copy. BELMAC shall not make any further use of all information, data, know-how and the like received from ETHYPHARM either directly or indirectly and shall take all necessary step to ensure that any of its employees who have had knowledge of the confidential information or benefited from the transfer of technology shall comply with their confidentiality obligations during and after their employment contract with BELMAC.

BELMAC will have the right to deliver the Products with respect to any orders placed by ETHYPHARM or BELMAC or BELMAC's Licensees and accepted by BELMAC before the date of termination of this Agreement.

Upon termination of this Agreement, whatever the reason, ETHYPHARM shall make sure that BELMAC's needs and BELMAC's Licensees needs in Omeprazol Product shall be fulfilled from one of ETHYPHARM's production sites in order to avoid shortage of said Omeprazol Product on the market. Conditions of delivery in such event shall be those agreed upon between the parties hereinunder (clause 12.) , unless otherwise mutually agreed by the Parties.